Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **Ethicon Wave 1 cases listed in Exhibit A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DOUGLAS GRIER, M.D.

Plaintiffs respectfully request that the Court preclude defense expert Douglas Grier, M.D., a urologist, from giving opinions on (1) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; (2) his statements about the safety and efficacy of Defendants' products based on his own practice; and (3) the adequacy of Defendants' product warnings and instructions for use ("IFU").

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues

in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Grier from giving the opinions referenced above because he is not qualified to opine on those issues and has not done the necessary research to produce opinions that can reliably be applied to this case.

Dr. Grier has issued four lengthy reports in this litigation addressing the following five products: TVT and TVT-O, TVT-S, Prolene Soft and Prolift (the "subject products"). All of these reports contain the same general opinions/statements:

- The products at issue were not defective, were reasonably safe for their intended use, and had a positive benefit-to-risk profile. Dr. Grier opines that the benefits of Defendants' products outweigh the risks of using them, and each product is safer and better than non-mesh alternatives. The products could not have been made safer for their intended uses at the time they were launched, and the products were state of the art when launched. (Prolift Report, attached as Exhibit B, at 24; Prolene Soft Report, attached as Exhibit C, at 19; TVT/TVT-O Report, attached as Exhibit D, at 29; TVT-S Report, attached as Exhibit E, at 34-35).
- Dr. Grier opines about his experience in his own practice related to the safety and efficacy of Defendants' product at issue. (*See, e.g.*, Prolift Report, Ex. B, at 15-16; Prolene Soft Report, Ex. C, at 11-12; TVT/TVT-O Report, Ex. D, at 13-14).

- The IFU and/or the warnings concerning Defendants' subject product are adequate and allow for the safe use of the device. (Prolift Report, Ex. B, at 20; Prolene Soft Report, Ex. C, at 16; TVT /TVT-O Report, Ex. D, at 22; TVT-S Report, Ex. E, at 28).

The first bullet point does not use the word "design," but it clearly is an opinion about the subject products' design. The first point recites the legal test on a design defect claim in West Virginia. *See Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 683 (W. Va. 1979) (stating that "the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not **reasonably safe for its intended use**" (emphasis added)). The second clause addresses the risk-utility test, which the focus of the design defect inquiry in many states. *See, e.g.*, *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823, 836 (Pa. 2012); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010); *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008); *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1150 (Md. Ct. App. 2002); *Cavanaugh v. Skil Corp.*, 751 A.2d 564, 580 (N.J. Super. App. Div. 1999), *aff'd*, 751 A.2d 518 (N.J. 2000). The next point addresses the utility of alternative designs, which generally factor into the design defect analysis in some manner. *See, e.g.*, *Branham*, 701 S.E.2d at 14; *Hernandez*, 2 S.W.3d at 258; *Halliday*, 792 A.2d at 1150.

The second bullet point relates to Dr. Grier's attempt to bolster his design defect opinion based on his own experience as to the safety and efficacy of Defendants' products. As discussed in greater detail below, this is Dr. Grier's attempt to backdoor into evidence an improper and unsupported opinion on his personal complication rate.

The final bullet point contains an opinion expressly directed to the adequacy of the warnings and IFU accompanying the subject products.

For the reasons described below, Dr. Grier should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. Dr. Grier should be precluded from giving design opinions.

a. Dr. Grier expressly testified he is not a design expert.

The first reason, and perhaps the most important reason, that Dr. Grier should be precluded from opining about the design of the subject products is that he admits he is not an expert on design:

> Q (By Mr. DeGreeff) Let's try this again. Doctor, yes, no, or you cannot answer my question as it's phrased: Are you holding yourself out as an expert in the design of transvaginal mesh products?
>
> MR. KOOPMANN: Same objection.
>
> THE WITNESS: No, I'm not a design expert.

(March 22, 2016 Deposition of Douglas Grier ("Grier Deposition"), portions attached as Exhibit F, at 68:21-69:2).

> Q Are you qualified to give -- you're not holding yourself out as an expert on the area of design, are you?
>
> MR. KOOPMANN: Objection to form.
>
> THE WITNESS: No.
>
> Q (By Mr. DeGreeff) I mean, you've never designed a medical device; correct?
>
> A Correct.

(*Id.* at 128:22 – 129:3).

> Q You don't have any patents on medical devices?
>
> A No.

(*Id.* at 129:7-8).

Even during defense counsel's attempt to rehabilitate him, Dr. Grier once again confirmed his lack of design expertise:

Q You don't hold yourself out to the community as a design expert; is that fair?

A That is fair.

(*Id.* at 329:3-5).

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Grier, who admitted on multiple occasions during his recent deposition that he is not an expert on design. As such, he should be precluded from giving any opinions related to design of the subject products.

b. Dr. Grier did not review Defendants' key documents related to product design, and even if he had reviewed them Dr. Grier has no base of knowledge as to what those documents would demonstrate.

Dr. Grier should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. In the Boston Scientific litigation, Boston Scientific Corp. ("BSC") moved to exclude Dr. Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that "regardless of the literature he has reviewed or the experience he has

gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

The same analysis applies to Dr. Grier in this case. He confirmed repeatedly that he did not review Defendants' internal design documents in formulating his opinions because he did not find them "relevant":

> Q (By Mr. DeGreeff) Did you -- in rendering your opinions, did you rely at all on internal company documents?
>
> A No.
>
> Q Why not?
>
> A I don't find them necessarily relevant.
>
> Q Why are they not relevant?
>
> A Well, because a lot of it has to do with research and development early on in the development of the products, and quite frankly, it's not -- I don't find it relevant for me in rendering an opinion.

(Grier Deposition, Ex. F, at 43:17 – 44:1).

> Q So my question is about design documents that would be relevant to the products that we're here about. Do you remember reviewing any of those design documents?
>
> A Not specifically.

(*Id.* at 45:10-13).

> Q Okay. So my question was a little different than that. Have you reviewed -- and I don't care when you reviewed them. Have you reviewed all of the … documents that are in that binder?
>
> A Well, no. The ones I haven't reviewed were the pre-FDA design documents, which are very tedious, and I didn't find relevant.

Q So fair to say, you did not review the design documents that were relied on by Ethicon for approval by the FDA?

MR. KOOPMANN: Objection to form.

THE WITNESS: That's true.

Q (By Mr. DeGreeff) Anything else?

A Well, there's just a bunch of minutes and discussions by, I guess, engineers within the—within the company on the product specifications and the launch of the product.

Q And did you review those?

A I did not.

Q Why not?

A Well, because I don't find it relevant.

Q And that's the—those are memos done by the engineers who designed the product?

A Correct.

Q Why did you not find that relevant?

A Well, because it's tremendously tedious, and it's not clinically relevant. It was how they developed the product and—the device, and it's kind of too technical for my interest.

Q And you didn't—so you didn't review that in rendering your opinions?

A No.

(Grier Deposition, Ex. F, at 65:8-66:12). In fact, he did not review Defendants' internal documents globally because he did not find them relevant. (*Id.* at 316:5-13). Because he did not review the relevant design documents, Dr. Grier lacks the required knowledge to give a reliable opinion about the design of Defendants' transvaginal mesh products.

Moreover, Dr. Grier conceded that he could not recall reviewing the design history file for Defendants' products:

Q Well, have you reviewed the design device file?

MR. KOOPMANN: Objection. Form.

THE WITNESS: I don't recall.

(Grier Deposition, 44:17-19). As the name suggests, the design history file would include all of the information about the design of the product. The necessary components of a design history file are laid out in 21 C.F.R. § 820. *See* 21 C.F.R. § 820.1 ("The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."). Defendants' research and design engineer Katrin Elbert, Ph.D., testified that the design history file is "the archive of all the documents that show us the history of the design of the product. It contains all of our design control documents, and it's also what we use to support regulatory submissions." (12-23-14 Elbert Dep., portions attached as Exhibit G, at 270:5-11). Dr. Grier's failure to review such important documents leaves him without a reasonable foundation for opinions about the design of the subject products. In addition, Dr. Grier had not heard of MedScand, which is the company that partnered with Ulf Ulmsten in developing the TVT, one of the subject products. (Grier Deposition, Ex. F, at 129:15-17).

Dr. Grier also confirmed he has not read the failure modes and effects analysis for the subject products, has never been involved in one, does not believe those analyses to be pertinent evidence, and does not know what that phrase means. (Grier Deposition, Ex. F, at 135:19 – 137:3, 138:5-19, 331:9-11). As discussed in the deposition of Defendants' medical director Charlotte Owens, the purpose of a design failure modes and effects analysis ("dFMEA") is to

"review the potential risk associated with the design of the product." (9-13-12 Owens Dep., portions attached as Exhibit H, at 485:14-24).[1]

> Q. And when you say "associated with the design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?
>
> A. Correct.

(*Id.* at 485:25-486:7).

> Q. And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?
>
> A. Yes, all that we could conceive of, yes.

(*Id.* at 449:12-22). Dr. Grier should have reviewed these documents in forming his opinions about the design of the subject products; but not only did he fail to review those documents, he did not even know what the phrase "failure modes and effects analysis" means.

All this being said, even if Dr. Grier had reviewed the relevant design documents, he does not even know what product design documents are:

> Q Well, do you know what I'm talking about when I say design documents?
>
> A Not precisely, no.

(Grier Deposition, Ex. F, at 44:12-14). Given this fact, he would not have been able to interpret and use those documents in rendering opinions regardless of whether he read them. This is confirmed by his testimony that the design documents are "tedious" and "too technical for his interest." (*Id.* at 66:5-9).

[1] Ms. Owens's cited deposition related to the Prolift product only, but the discussion quoted was not product-specific.

Based on the foregoing, Dr. Grier's opinions on the issue of product design should be excluded.

II. Dr. Grier's statements about his personal experience related to the safety and efficacy of the subject products should be excluded because he has kept no records on those points, and this information exist only in his mind.

Dr. Grier should be precluded from testifying about his perceived safety and efficacy rates with the subject product from his own practice, as that information exists only in Dr. Grier's head and is entirely unsupported by any statistical information/analysis. As an example, Dr. Grier's Prolift report includes the following statement:

> I have personally performed over 1,000 procedures involving implantation of Prolene polypropylene mesh for treatment of stress urinary incontinence or pelvic organ prolapse, and have found the Prolene polypropylene products to be safe and efficacious when following the appropriate patient selection and the technique described by the product instructions for use and sound medical judgment and surgical technique and concepts … . The devices are high quality, straightforward, and the polypropylene mesh is stable over time, as I have patients implanted 15 years ago and see no long-term complication trends … . The overwhelming majority of those anxious patients have excellent outcomes and no adverse symptoms.

(Grier Prolift Report, Ex. F, at 15-16). Defendants have now caught on to the fact that their experts' opinions about complications rates among their own patients are inappropriate, unsupported and inadmissible, so Dr. Grier now seeks to backdoor essentially the same opinion by excluding a precise complication rate. This should not be permitted, as Dr. Grier lacks any data or analysis to support his conclusions:

> Q So do you have something in your office where you track the reason for each removal and what product it is you're removing?
>
> A Their medical records.
>
> Q Is that a list you would keep in your office somewhere?
>
> A It's one I could retrieve.

Q So you have a list currently kept in your office of the product you removed and with -- with the reason for removal?

A No, I don't have a list.

(Grier Deposition, Ex. F, at 143:10-19).

Q That was going to be my question. Where's the tracking data on TVT-Rs that were removed, on the number of explants you've done?

A What do you mean by "tracking data"?

Q Is that something you keep track of in your office?

A No, I don't keep track of the numbers.

(*Id.* at 144:14-19).

Q Doctor, do you do anything within your office to track what percentage of the women that you do implants in are lost to follow-up?

A No.

….

Q And a lot of patients aren't comfortable going back to the person who put in an implant that gave them complications; fair?

A That's -- complications in general, for all of medicine, a lot of times patients have unrealistic expectations and will go elsewhere when they don't have exactly the outcome that they want. That's very common, not just in this.

Q Okay.

A It's common with all complications.

(*Id.* at 146:12-15, 147:6-15).

Q And what was the point of this email? What was – what were you trying to tell her with that?

A I was -- I saw a rolling -- a rolling average of what I had spent for slings, and so I was kind of shocked by that number. I can't remember what they cost, but that's the equivalent of 100 -- probably 100 slings -- surgeries.

> So I -- just like I don't count what -- what I've been paid, I normally don't count how many slings that I've done in a given year. And so this was toward the end of the year, and it looks like I did 100 slings.

(*Id.* at 268:18 – 269:3).

This testimony speaks for itself. Dr. Grier is asserting and relying on alleged safety and efficacy data from his own practice, and yet he has no foundation whatsoever for that assertion. He does not track the reason for removal or the transvaginal mesh product removed, the number of removals for various products, the total number of transvaginal mesh implants he performs, or the percentage of the patients in whom he implanted transvaginal mesh products that are lost to follow up (i.e. go to another doctor for removal). As such, any estimates about safety rates from Dr. Grier's practice are extremely unreliable, and Plaintiffs have no reasonable way of testing the veracity of his claims, which exist only in his mind. Because there is no foundation for this testimony, Dr. Grier should be prohibited from providing this testimony. Allowing him to do so would be akin to permitting an improper opinion about his personal complication rates.

III. Dr. Grier admits that he has no expertise in the area of warnings and IFUs, and his opinions on those issues should be excluded.

As discussed in Section I, above, this Court has recognized the importance of an expert's admission that he is not an expert in the area of warnings. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611. Just like his design opinions, Dr. Grier's opinions concerning the adequacy of the warnings and IFUs for the subject product should be excluded because he admits he is not an expert:

> Q Doctor, you're not an expert on warnings, are you?
>
> MR. KOOPMANN: Objection. Form.
>
> Q (By Mr. DeGreeff) Medical device warnings?
>
> MR. KOOPMANN: Same objection.

THE WITNESS: No.

(Grier Deposition, Ex. F, at 127:25 – 128:4). Dr. Grier confirmed this again during defense counsel's attempt to rehabilitate him:

> Q And you don't hold yourself out to the community as a warnings expert; correct?
>
> A No, I don't.

(*Id.* at 329:11-13). Additionally, Dr. Grier did not review the November 2015 deposition of the 30(b)(6) witness chosen by the Defendants to testify on the revised IFUs for their products. (*Id.* at 356:5-19).

Dr. Grier has clearly admitted he is unqualified to give opinions on the adequacy of Defendants' warnings and IFUs, and has failed to the proper research necessary to give those opinions. Therefore, Dr. Grier's opinions on this issue should be precluded.

CONCLUSION

Based on the foregoing, Dr. Grier should be precluded from giving opinions on (1) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; (2) his statements about the safety and efficacy of Defendants' products based on his own practice; and (3) the adequacy of Defendants' product warnings and IFUs.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell
Attorney for Plaintiffs